

SPINAL STABILIZATION SYSTEMS

FIELD OF THE INVENTION

[0001] The present invention provides devices for the stabilization of the spinal column. In particular, the present invention provides spinal stabilizing elements and spinal stabilization systems that combine an intervertebral disc prosthesis with a variety of trans-vertebral stabilizing elements to retain, at least in part, the natural physiological degrees of motion of the spine.

BACKGROUND OF THE INVENTION

[0002] Degenerative disc disease, spinal trauma and tumors are common and painful conditions suffered by a significant portion of the population. In some instances, the pain and complications caused by these conditions may be bad enough to require that one or more vertebra, facet joints, and/or intervertebral discs be removed from the spinal column. In these instances, arthrodesis or bone fusion are common treatments used to facilitate the realignment and/or fixation of the spinal elements. Typically, two types of assemblies are known for securing one or more vertebra in order to obtain arthrodesis or bone fusion. The first type of assembly generally includes two posterior vertebral plates disposed longitudinally on either side of the spinous processes. Each plate is attached between adjacent vertebra using bone anchoring elements, such as bone screws. Together the plates provide a rigid vertebral fixation. The second type of stabilizing assembly generally includes two posterior vertebral rods disposed longitudinally on either side of the spinous processes. Like the plates, these rods are attached between adjacent vertebra using appropriate bone anchoring elements to provide a rigid vertebral fixation.

[0003] One drawback of rigid fixation derives from the fact that significant loads are placed on the stabilizing assemblies and particularly on the anchoring sites thereof. These loads may result in the loosening of the assembly from the vertebra or even the breaking of the assembly. The stabilizing assemblies are often supplemented with bone grafts formed from transplanted bone tissue and/or artificial fusion cages in order to fuse the adjacent vertebra. Unfortunately, such bone grafts and fusion can cause serious complications throughout the patient's life because fusing the vertebra subjects the remaining spinal elements to high stress and degeneration. This is particularly true of the remaining adjacent vertebra and vertebral discs because these elements must accommodate an even greater degree of motion. Moreover, spinal fusions limit the range of motion for patients in flexion, extension, rotation and lateral bending.

[0004] Similar assemblies are also used to correct spinal deformities, such as those associated with scoliosis, spinal traumas and tumors. In these systems correcting rods spanning two or more vertebra are typically implanted on either side of the spinous processes.

[0005] In addition to rigid spinal stabilization assemblies, some semi-rigid devices have been proposed. Some such devices are aimed at preserving a small amount of intervertebral elasticity in order to assist in subsequent bone fusion and to reduce stress. Other such devices provide stabilizing rods that are capable of sliding in a vertical direction with respect to the vertebra in order to accommodate spinal column growth.

[0006] Because of the problems associated with rigid vertebral fixation, the use of artificial disc prostheses has become an attractive option to many patients. These disc prostheses may be inserted in place of a natural vertebral disc in order to simulate at least some of the natural intervertebral movement and to restore proper disc height. Ideally, a disc prosthesis will operate in conjunction with the facet joints to restore the full range of motion of the spine. The facet joints are posterior vertebral elements that help to support axial, torsional and shear loads that act on the spinal column. When a facet joint becomes diseased or deformed (e.g. enlarged), it is

sometimes necessary to remove part or all of the facet joint in a full or partial facetectomy. Unfortunately, the removal of the facet joint may destabilize the spinal column by decreasing the stiffness in flexion, extension, lateral bending and rotation. Moderate or advanced facet disease and facetectomies, or other prior destabilizing procedures, may be a contraindication for prosthetic discs.

[0007] Thus, a need exists for a spinal stabilization system that preserves at least some of the physiological mobility of the vertebra, vertebral discs, and facet joints after a prior destabilizing procedure, such as a facetectomy or laminectomy.

SUMMARY OF THE INVENTION

[0008] Spinal stabilizing elements and spinal stabilization systems are provided herein. The stabilization systems combine at least one disc prosthesis and/or at least one disc nucleus replacement with one or more stabilizing elements to retain or simulate at least some of the physiological intervertebral mobility of the spine by distributing the stress and mobility functions between the disc prosthesis or disc nucleus replacement and the stabilizing elements. Specifically, the systems provide a disc prosthesis or disc nucleus replacement capable of retaining or simulating at least one motion of a natural intervertebral disc while simultaneously providing a trans-vertebral stabilizing element capable of retaining or simulating at least one motion of a natural facet joint. In some embodiments, the stabilizing elements are capable of preserving or simulating flexion, extension, lateral bending, compression and rotation of the spine.

[0009] The stabilization systems include a trans-vertebral stabilizing element disposed outside of the intervertebral space between adjacent vertebrae in the spine to provide an intervertebral support. This element serves to bear a portion of the load on the spinal column while maintaining a degree of mobility between the adjacent vertebra.

[0010] One aspect of the invention provides a spinal stabilization system wherein the stabilizing element includes a first segment that is anchored to a first

vertebra by a first connector and a second segment anchored to another vertebra by a second connector. The two segments are connected by a joint that provides the stabilizing element with at least one degree of motion, such as a rotation, a compression, an extension, a flexion and/or a bending motion. Suitable stabilizing elements include, but are not limited to, rods and plates.

[0011] The joint used to connect the segments of the stabilizing element may be any joint that is capable of providing a degree of motion between the two segments of the stabilizing element. In some instances the joint is a pivoting joint. In other instances the joint is a compressible joint.

[0012] In some instances, the intervertebral stabilization system will include only a single stabilizing element disposed longitudinally on one side of the spinous processes. However, in other embodiments, the intervertebral stabilization system desirably includes two stabilizing elements disposed longitudinally in a substantially parallel relationship on opposite sides of the spinal processes. In this latter embodiment, the two stabilizing elements may be connected by a transverse connecting rod that desirably, but not necessarily, includes a pivoting joint.

[0013] The stabilizing element is used in conjunction with a disc prosthesis or a disc nucleus replacement disposed between adjacent vertebra in a spinal column. The disc prosthesis may be any suitable prosthesis capable of retaining or simulating at least one natural intervertebral motion. The disc prosthesis that is used in conjunction with the stabilizing elements may have a variety of designs, many of which have been proposed in the literature. Suitable disc prostheses include, but are not limited to, those that include a ball-in-socket mechanism, those that include a mechanical damping mechanism, and those that include a flexible or elastomeric polymer insert.

[0014] In one embodiment, a spinal stabilization system includes a stabilizing element comprising a first segment and a second segment connected by a pivoting joint. The first segment is attached to a first vertebra by a first connector and the second segment is attached to a second vertebra by a second connector, such that the

stabilizing element adopts a substantially parallel alignment with respect to the longitudinal axis of the spinal column. The pivoting joint may take on a variety of forms, provided it allows the stabilizing element to undergo a bending or flexion/extension motion at the joint. In one exemplary embodiment, the stabilizing element is composed of two segments, wherein a proximal end of the first segment defines a ball and a proximal end of the second segment defines a complimentary spherical socket. In this construction, the ball and socket fit together to provide a pivoting joint.

[0015] In another exemplary embodiment, the stabilizing element is composed of two segments, wherein a socket defined by two opposing concave surfaces separated by a gap extends into the proximal end of the first segment. An insert characterized by two opposing convex surfaces extends outwardly from the proximal end of the second segment. The insert is adapted to fit into the socket to provide a pivoting joint based on a ball-and-socket type mechanism.

[0016] Another aspect of the invention provides a spinal stabilization system that includes at least one dynamic stabilizing element in combination with a disc prosthesis. As used herein, a “dynamic” stabilizing element is an element that allows for at least one natural intervertebral motion when it is disposed along a spinal column. Like the jointed stabilizing elements provided herein, the dynamic stabilizing elements may be used to stabilize the spinal column while preserving or accommodating at least some of the natural motions of a facet joint after a prior destabilizing procedure, such as a facetectomy. Unlike the jointed stabilizing elements, these dynamic stabilizing elements do not require a joint to provide motion. Suitable dynamic stabilizing elements have been proposed for correcting spinal deformities, such as those related to scoliosis, or for relieving pressure on a damaged disc. However, it has not been recognized previously that such dynamic stabilizing elements may advantageously be used in combination with one or more disc prostheses or disc nucleus replacements in order to stabilize a spine without partially or wholly sacrificing natural intervertebral and facet joint motion.

[0017] Like the jointed stabilizing elements, the dynamic stabilizing elements will typically be located at the posterior of the spine, but other placements, including lateral and anterior placements, are possible. The dynamic stabilizing elements may further be attached to various areas of the vertebrae including the main body of the vertebrae, the spinous process and the facet joint, and may be implanted by an open procedure, endoscopically or laprascopically.

[0018] In one embodiment of this aspect of the invention, the dynamic stabilizing element includes a curved rod attached to a first vertebra by a first connector and to a second vertebra by a second connector. The connectors are coupled to the curved rod in a manner that allows for translation of the rod along the axis of curvature of the spine. The dynamic stabilizing element further may include a damping element, such as a spring, working in conjunction with the dynamic stabilizing element to damp axial loading, or to restrict the motion of the rod. between the vertebrae.

[0019] In some embodiments of this aspect of the invention, the spinal stabilization system includes two or more dynamic stabilizing elements in combination with the disc prosthesis. Here, each dynamic stabilizing element includes a damping element, such as a spring, connected between a first and second vertebra by a first connector and a second connector. The connectors may include pedicle screws, lateral mass screws, hooks, polyaxial pedicle screws, polyaxial hooks, or the like.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1 shows a cross-sectional view of a stabilizing element having a ball-and-socket type joint.

[0021] FIG. 2 shows a cross-sectional posterior view of the two segments of a stabilizing element that come together to form a pivoting joint, wherein the stabilizing element is a stabilizing rod.

[0022] FIG. 3 shows a posterior cross-sectional view of the two segments in FIG. 2 connected to form a pivoting joint.

[0023] FIG. 4 shows a posterior view of the stabilizing element of FIG. 3.

[0024] FIG. 5 shows a lateral cross-sectional view of the stabilizing element of FIG. 3.

[0025] FIG. 6 shows a stabilizing element having a tilted pivoting joint.

[0026] FIG. 7 shows a stabilization system implanted in a spine, including the stabilizing element of FIGS. 2-5 and a disc prosthesis.

[0027] FIG. 8 shows a posterior view of a spinal stabilization system implanted in a spine, including two stabilizing elements of the type shown in FIGS. 2-5 and an articulating transverse connector.

[0028] FIG. 9 shows a lateral view of a stabilizing element having damped flexion, extension, and translational motions.

[0029] FIG. 10 shows a posterior view of the stabilizing element of FIG. 9.

[0030] FIG. 11 shows a cross-sectional posterior view of the two segments of the stabilizing element that come together to form a pivoting joint, wherein the stabilizing element is a stabilizing plate.

[0031] FIG. 12 shows a lateral cross-sectional view of the stabilizing element of FIG. 11.

[0032] FIG. 13 shows a cross-sectional posterior view of the stabilizing element wherein the two segments that connect to form a pivoting joint are each composed of multiple sections.

[0033] FIG. 14 shows a stabilizing element composed of two segments connected together by a compressible joint, wherein the stabilizing element is a stabilizing rod.

[0034] FIG. 15 shows a cross section of a polyaxial pedicle screw that may be used as a connector.

[0035] FIG. 16 shows a cross section of a polyaxial hook that may be used as a connector.

[0036] FIG. 17 shows a posterior view of a spinal stabilization system that includes two dynamic stabilizing elements.

[0037] FIG. 18 shows a cross-sectional lateral view of the spinal stabilization system of FIG. 17, including a disc prosthesis.

[0038] FIG. 19 shows a dynamic stabilizing element composed of a spring protected by a housing.

[0039] FIG. 20 shows a spinal stabilization system that includes a disc prosthesis and two spinal stabilizing elements of the type shown in FIG. 19 attached to the anterior of a spinal column.

[0040] FIG. 21 shows a spinal stabilization system that includes a disc prosthesis and two spinal stabilizing elements of the type shown in FIG. 19 attached to opposite sides of the spinous processes.

[0041] FIG. 22 shows a spinal stabilization system that includes a disc prosthesis and two spinal stabilizing elements of the type shown in FIG. 19 attached across a pair of facet joints.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0042] Non-rigid spinal stabilizing elements and spinal stabilization systems which combine the spinal stabilizing elements with disc prostheses or disc nucleus replacements are provided herein. The spinal stabilization systems are designed to retain or simulate at least some of the physiological intervertebral mobility of the spine by distributing the stress and mobility functions between one or more disc prostheses or disc nucleus replacements and one or more stabilizing elements. The

stabilizing elements and stabilization systems provided herein are useful for stabilizing the cervical, thoracic and lumbar regions of the spine, may be combined with one or more prosthetic vertebral bodies and may be used to preserve the natural mobility of a facet joint in patients with facet disease or patients who have had a prior destabilizing procedure, such as a facetectomy or a laminectomy.

[0043] A first aspect of the invention provides a spinal stabilization system that includes the following basic elements: 1) a segmented stabilizing element composed of at least two segments; 2) a joint connecting the at least two segments of the stabilizing element; 3) a first connector adapted to connect the stabilizing element with a first vertebra in a spinal column; 4) a second connector adapted to connect the stabilizing element to a second vertebra in the spinal column; and 5) a disc prosthesis or disc nucleus replacement adapted to be inserted into an intervertebral space between two adjacent vertebra in the spinal column. Each of these basic elements will be described in more detail below.

[0044] The stabilizing elements of the spinal stabilization system are designed to stabilize the spine by relieving some of the stress on an intervertebral disc prosthesis and to preserve at least some of the natural motion of one or more facet joints. The stabilizing elements are a trans-vertebral stabilizing element. As such, the stabilizing elements span two or more vertebra in the spine and are located outside of the intervertebral spaces in the spinal column. The stabilizing elements will typically be located at the posterior of the spine, but other placements including lateral and anterior placements are also possible. The stabilizing elements may be implanted by an open procedure, endoscopically or laparoscopically. The spinal stabilization systems may include a single stabilizing element or two or more stabilizing elements. When only a single stabilizing element is included, that stabilizing element is generally disposed posteriorly to one side of the spinous processes. When two stabilizing elements are included in the system, they are typically disposed in a spaced apart, substantially parallel arrangement wherein one of the stabilizing elements is placed on either side of the spinous processes. In spinal stabilization systems that include two or more stabilizing elements, the elements optionally may be connected

together through a transverse connector. Like the stabilizing elements, the transverse connectors may be composed of two or more segments connected together by a joint, typically a pivoting joint.

[0045] The stabilizing elements are typically rods or plates having a long dimension that runs along the long dimension of the spine when the stabilizing element is implanted in a patient. Spinal stabilizing rods and plates have been described in the literature. These include, but are not limited to, the rods described in U.S. Patent Nos. 6,554,831 and 4,743,260, the disclosures of which are incorporated herein by reference. Also included are the plates described in published U.S. Patent Application No. 2001/0037111 and U.S. Patent No. 5,352,224, the disclosures of which are incorporated herein by reference. These rods and plates may be adapted for use as stabilizing elements in the present invention by inserting one or more connecting joints along their lengths.

[0046] Each segment of the stabilizing element may be composed of a single integrally formed unit. Alternatively, one or more of the segments may be sectional, that is, composed of a plurality of interlocking sections. For example, the segments of a stabilizing rod may be divided into sections that screw together end to end. This design allows the length of a segment to be tailored to fit a particular patient or a particular placement of the stabilizing elements along a spine. In addition, this design makes it possible to easily switch out the sections that form the joint for rigid sections. This may be a desirable option, for example, when a disc prosthesis is exchanged for or converted into a fusion. Additionally, the segments may be adapted to be inserted into pre-existing stabilizing devices.

[0047] The at least two segments of the stabilizing element are connected by a joint. In this configuration, the joint serves at least two purposes. First, the joint serves to fasten the two segments of the stabilizing element together, and second, the joint provides for at least one degree of motion between the two segments. For example, the joint may be designed to provide or accommodate spinal flexion and extension and/or a lateral bending motion. For the purpose of this disclosure, a joint that provides or accommodates a flexion and extension and/or a lateral bending

motion is referred to as a pivoting joint. Alternatively, the joint may provide, accommodate, or damp spinal compression/expansion type motion. For the purposes of this disclosure, a joint that provides, accommodates, or damps a spinal compression/expansion motion is referred to as a compressible joint. In some embodiments, the joint may provide or accommodate a combination of the above-mentioned motions. In some instances, it is desirable to provide restrictive elements that restrict the extent of motion provided by the joint in order to more accurately simulate the natural motion of the spine.

[0048] Suitable pivoting joints include ball-and-socket type joints and joints based on a ball-and-socket type mechanism (i.e., joints including complimentary concave and convex surfaces). Spinal stabilizing elements including pivoting joints for use in combination with bone fusions have been proposed. These spinal stabilizing elements may be used in combination with one or more intervertebral disc prostheses or one or more disc nucleus replacements to provide a spinal stabilization system in accordance with the present invention. A jointed intervertebral link device that may be used as a stabilizing element in the spinal stabilization systems provided herein is described in U.S. Patent No. 6,241,730, the entire disclosure of which is incorporated herein by reference. Briefly, the pivoting joint of the '730 patent includes a socket extending into the proximal end of a first segment and a pin extending outwardly from the proximal end of a second segment, the pin having a distal end and an outwardly extending radial collar. A first damping element is disposed around the pin above the collar and a second damping element is disposed around the pin below the collar. The pin and the first and second damping elements extend into the socket to form a joint that allows for multidirectional pivoting of the pin in the socket.

[0049] Another suitable ball-and-socket joint design is described in reference to a jointed cross-link for an implantable spinal apparatus in U.S. Patent No. 6,554,831 (see, e.g., FIG. 4), the entire disclosure of which is incorporated herein by reference. This joint is based on a ball-and-socket mechanism wherein a first segment has a proximal end defining a socket for receiving a ball integrally formed at the

proximal end of a second segment. Together, the ball-and-socket provide a pivoting joint that connects the two segments. This type of joint may be used as a pivoting joint in a transverse connector. Other illustrative joint designs are shown in FIGS. 2-13, discussed in greater detail below.

[0050] Connectors are used to attach the stabilizing elements along the spinal column. The connectors may include any suitable connecting means capable of securing a stabilizing element to a vertebra. Suitable connectors include, but are not limited to, pedicle screws, hooks, and lateral mass screws. The connectors will typically include a shaft, such as a rod, hook, nail or threaded screw shaft, that is adapted to penetrate or anchor to a bone and a securing portion adapted to secure the stabilizing element. For example, the connector may be a bone screw having a coarse thread on one end for threading into a bone and a machine thread on the opposing end for screwing into a matching tapped bore in a stabilizing element. The connector may itself include multiple elements. For example, the connector may include a screw or hook secured to a rod clamp for connecting a stabilizing rod to a bone.

[0051] In some embodiments, the connectors include polyaxial screws or hooks. Such screws or hooks allow for the accommodation of differing orientations and positioning between screws implanted in a series and may provide one or more degrees of motion between the connectors and the stabilizing elements to which they are attached. Suitable polyaxial pedicle screws and hooks for use as connectors in the spinal stabilization systems provided herein are disclosed in U.S. Patent Nos. 5,591,166, 5,628,740, and 6,626,908 the entire disclosures of which are incorporated herein by reference. In order to provide for an articulating connection, the polyaxial pedicle screws disclosed in U.S. Patent Nos. 5,591,166 and 5,628,740, may be used without being locked into a fixed orientation such that the stabilizing elements retain a relative motion with respect to the shaft of the connector.

[0052] The connectors desirably, but not necessarily, provide a rotatably adjustable connection to the stabilizing elements. As used herein, a rotatably adjustable connection refers to a connection that allows the stabilizing elements, or individual segments thereof, to be rotated about their longitudinal axes before, during

or after implantation of the spinal stabilization systems in order to allow the surgeon to optimize the orientation of the joint relative to the patient's spine. The connectors may include a locking mechanism adapted to lock-in the orientation, preventing further rotation once the orientation of the stabilizing element has been optimized. The pedicle screws described in U.S. Patent Nos. 5,591,166 and 5,628,740, would be capable of serving this function. In one such embodiment, the stabilizing element is a rod and the connector is a screw including a threaded shaft and a head having a lateral (i.e., perpendicular to the long axis of the shaft) bore extending therethrough. The diameter of the rod is small enough to allow the rod to pass through the bore and rotate therein. Once the rotational orientation of the rod has been optimized, a set screw, or other locking mechanism, is provided to clamp down on, or screw into, the rod, fixing its rotational orientation.

[0053] The connectors may be used to connect the stabilizing elements to adjacent or non-adjacent vertebrae in a spinal column. The connectors are desirably, but not necessarily, attached to same vertebrae between which the disc prosthesis or disc nucleus replacement is disposed or to a prosthetic vertebral body or bodies. In some instances, the connectors may be associated with pre-existing stabilizing devices, such that the stabilizing elements provided herein may be incorporated into or replace components of such devices.

[0054] In the spinal stabilization systems, the stabilizing elements are used in conjunction with at least one disc prosthesis or at least one disc nucleus replacement. In these systems, the prosthesis or replacement is contained within an intervertebral space that is spanned by one or more stabilizing elements. A variety of intervertebral disc prostheses may be used in conjunction with the spinal stabilization elements provided herein. Many such disc prostheses have been proposed. For example, the disc prosthesis may include a mechanical damping element, such as a spring, disposed between an inferior base plate adapted to be attached to an inferior vertebra, and a superior base plate adapted to be attached to a superior vertebra. Alternatively, the disc prosthesis may include a rubber, gel, or polymeric insert disposed between an inferior and a superior base plate. The disc prosthesis may be based on a ball-and-

socket mechanism wherein one or more pairs of complementary concave and convex surfaces come together to form a joint. Suitable disc prostheses that may be used in the spinal stabilization systems provided herein include, but are not limited to, those described in U.S. Patent Nos. 5,556,431; 5,401,269; 5,314,477; 6,368,350; 6,146,421; 6,139,579; and 5,562,738, the entire disclosures of which are incorporated herein by reference. Other suitable disc prostheses are described in U.S. Patent Application No. 10/675,573, filed September 30, 2003, the entire disclosure of which is incorporated herein by reference. The stabilizing elements may also be used with an artificial disc nucleus, such as a hydrogel-based nucleus replacement.

[0055] The spinal stabilizing elements and spinal stabilization systems provided herein may span a single intervertebral space between two adjacent vertebra, or may span multiple intervertebral spaces, and possibly multiple disc prostheses and/or disc nucleus replacements, along a patient's spine.

[0056] The spinal stabilization systems provided herein may also optionally include one or more prosthetic vertebral bodies spanned by one or more stabilizing elements. Suitable prosthetic vertebral bodies for incorporation into the spinal stabilization systems provided herein have been described in the literature. These include, but are not limited to, the prosthetic vertebral bodies described in U.S. Patent Nos. 4,932,975; 5,306,310; 5,147,404; 5,989,290; and 6,001,130, the entire disclosures of which are incorporated herein by reference. Another suitable vertebral prosthesis that may be used with the spinal stabilization systems provided herein is described in U.S. Patent Application No. 10/675,573, filed September 30, 2003. In embodiments where a prosthetic vertebral body is included, the connectors may connect the stabilizing elements to the prosthetic vertebral body or to a vertebra. Thus, as used herein, the phrases "connected to a vertebra" or "adapted to be connected to a vertebra" refer to connections to natural and artificial vertebrae.

[0057] FIGS. 1-13 show examples of pivoting joints that may be used to connect the first and second segments of a stabilizing element in the spinal stabilization systems provided herein. In FIGS. 1-10 and 13, a rod is used as an

illustrative stabilizing element. In FIGS. 11 and 12, a plate is used as an illustrative stabilizing element.

[0058] In the description of these figures, and throughout the specification, the terms “longitudinal” and “proximal” are used as relative terms. The term “longitudinal” is used to refer to the direction running lengthwise along the long dimension of a stabilizing element. The term “proximal” is used to refer to the location nearer to a joint.

[0059] The embodiments shown in the figures are intended only to exemplify the invention and should not be construed to limit the invention to any particular embodiment. The drawings are not necessarily to scale and the relative dimensions of the components of the stabilizing elements and the stabilization systems provided therein may deviate from those shown in the figures.

[0060] FIG. 1 shows a ball-and-socket type joint **100**. The joint depicted in FIG. 1 includes a first segment **102** having a generally spherical socket **106** extending into the proximal end thereof. The stabilizing element **100** further includes a second segment **104** having a ball **108** disposed on the proximal end thereof. The second segment **104** and the ball **108** are desirably, but not necessarily, integrally formed as one piece separated by a neck **110**. As shown in FIG. 1, the ball **108** and socket **106** fit together to provide a rotating joint.

[0061] When this joint is connected, the sidewalls of the spherical socket should extend upwardly beyond the maximum diameter of the ball in order to prevent the ball from becoming dislodged from the socket. As best seen in the blown-up section of FIG. 1, the socket is desirably characterized by a flat strip **109** extending laterally around its midsection in order to allow for translation in the longitudinal direction. The second segment **104** may optionally include a spring disposed around its neck in order to provide damping or restriction of translational, flexion, extension or lateral bending motions. The pivoting joint may be formed by press fitting the ball into the socket. Alternatively, diametrically opposed longitudinal slits (not shown) may be formed in the walls of the socket to provide the socket with a certain degree of

flexibility, thus enabling the ball to slide more easily into the socket. In the embodiment shown in FIG. 1, the neck **110** of the second segment **104** provides a certain amount of clearance between the first and second segments of the stabilizing element. The amount of clearance provided by the neck **110** can influence how far the two segments may pivot before coming into abutment and preventing further pivoting motion. The clearance provided by the neck **110** need not be uniform on all sides of the stabilizing element **100**. For example, the shape of the circumference of the neck **110** or the shape of the upper surface **111** of the second segment **102** may be designed to allow pivoting in some directions, but not in others. Thus, the stabilizing element may be designed to accommodate flexion and extension to a certain degree and lateral bending to a lesser degree.

[0062] FIGS. 2-6 depict an alternative embodiment of a pivoting joint that may be used to connect the two segments of the stabilizing element in a spinal stabilization system. FIG. 3 shows a cross-sectional front view of the stabilizing element. It should be understood that the “front” view may correspond to an anterior, lateral or posterior view, depending on the intended orientation of the stabilizing element in the patent’s spine. For purposes of illustration only, the front view in FIG. 3 may be considered to be a posterior view, such that the plane extending perpendicularly into plane of the figure and bisecting the stabilizing element may be referred to as the “sagittal” plane and the plane lying in the plane of the figure and bisecting the stabilizing element may be referred to as the “lateral” plane. In this embodiment, the stabilizing element includes a first segment **202** having a socket **205** extending into the proximal end thereof. This socket **205** is defined by two opposing concave surfaces **206**, **208** separated by a gap **210**. As best shown in the blown-up section of FIG. 2, the opposing concave surfaces desirably include a flat strip **221** running laterally through the apex of their concavity. The socket shown in FIG. 2 is further defined by a lower housing **212** centered on the longitudinal axis **214** of the stabilizing element and opening into the gap **210**. The stabilizing element further includes a second segment **204** having an insert **215** disposed on its proximal end. The insert is characterized by two opposing convex surfaces **216**, **218** and is desirably, but not necessarily, integrally formed on the proximal end of the second

segment **204**. As shown in the contrasting views of FIGS. 3 and 5, the insert is disc-shaped, that is, it is wider in one dimension than the other. This design is advantageous because it limits the rotation of the joint about its longitudinal axis **214**. The outermost end of the insert **215** desirably includes a flat extension **220**, while the opposing end forms a neck **222** in the second segment **204**.

[0063] FIG. 3 shows a pivoting joint formed by fitting the insert **215** into the socket **205** to connect the first segment **202** and the second segment **204** of the stabilizing element. This design allows the joint to pivot to a greater degree in the sagittal plane than in the lateral plane. The extent to which the joint may pivot in the sagittal plane will be determined, at least in part, by the clearance between the upper surface **211** of the first segment **202** and the shaft **213** of the second segment **204** provided by the neck **222** in the second segment. As shown in FIG. 4, the extent to which the joint may pivot may be increased by cutting a groove **400** into the proximal end of the first segment **202**. The flat extension **220** on the outmost end of the socket **205** may extend into the socket housing **212** in order to accommodate longitudinal translation of one segment with respect to the other. Optionally, a spring **300** may be inserted into the housing **212** of the socket **215** in order to damp axial loading on the joint. A side view of the stabilizing element of FIG. 3 is shown in FIG. 5.

[0064] The sockets extending into the proximal ends of the segments may be characterized by a central axis, which is the axis running through the center of the opening of the socket at the outermost end of the segment. In the embodiment depicted in FIGS. 2-5, the pivoting joint pivots about a central axis that coincides with a longitudinal axis **214** of the stabilizing element. However, in some applications, it may be desirable for the pivoting joint to pivot about a central axis that is not coincident with the longitudinal axis of the stabilizing element. Such an embodiment is depicted in FIG. 6. In this embodiment, the stabilizing element **600** includes a first segment **602** having a socket extending into its proximal end. This socket is defined in part by two opposing concave surfaces **606**, **608** separated by a gap. The stabilizing element **600** further includes a second segment **604** having an insert **615** disposed on its proximal end. The insert is characterized by two opposing convex

surfaces **616, 618**. Unlike the joints shown in FIGS. 2-5, the joint shown in FIG. 6 pivots about a central axis **622** that is not coincident with or parallel to the longitudinal axis **626** of the stabilizing element. Rather, the joint of FIG. 6 pivots about an axis **622** that forms an angle **624** with the longitudinal axis **626** of the stabilizing element. This design is advantageous because it allows a surgeon to optimize the orientation of the joint relative to the spinal column by rotating the first and second segments of the stabilizing element. In this manner, the pivoting joint may be properly aligned with the natural facet plane of each individual patient.

[0065] FIG. 7 shows a cross-sectional, lateral view of a spinal stabilization system that includes the spinal stabilizing element of FIGS. 2-5 in combination with an intervertebral disc prosthesis. The spinal stabilizing element is connected across a first vertebra **702** and a second vertebra **704** to one side of the spinal processes (shown in dotted lines) at the posterior of the spine. In the exemplary embodiment shown in FIG. 7, the stabilizing element is connected to the vertebrae using pedicle screws **706, 708**. The pedicle screws each include a screw head **710, 712** having a lateral bore extending therethrough. The first and second segments of the stabilizing element extend through the lateral bores in the first and second pedicle screw heads respectively. As shown in the figures, the first and second segments may be fixed to the pedicle screws by set screws **714, 716** that screw through the screw heads **710, 712** and press against or screw into or through the first and second segments of the stabilizing element. Of course, many other connectors and connector configurations may be used to attach the segments to the vertebrae.

[0066] The intervertebral disc prosthesis of the spinal stabilization system of FIG. 7 includes an inferior base plate **722** adapted to be connected to the inferior vertebra **704** and a superior base plate **720** adapted to be connected to the superior vertebra **702**. The inferior base plate is characterized by an upwardly-facing concave surface which faces an oppositely disposed concave surface of the superior base plate **720**. The disc prosthesis further includes a disc insert **724** sandwiched between the superior and inferior base plates **720, 722**. The disc insert **724** is characterized by two opposing convex surfaces which complement the concave surfaces of the superior and

inferior base plates **720, 722** in order to provide one or more degrees of motion between the superior and inferior vertebrae **702, 704**. A more detailed description of the disc insert is provided in U.S. Patent Application No. 10/675,573.

[0067] FIG. 8 shows a posterior view of the spinal stabilization system of FIG. 7. As shown in this figure, the spinal stabilization system includes two spinal stabilization elements disposed on opposite sides of the spinous processes. In the embodiment depicted in FIG. 8, the second segment **204** of the first stabilizing element and the second segment **804** of the second stabilizing element are connected by a transverse connector **806** which limits the ability of the two stabilizing elements to move independently with respect to each other. As shown in the figure, the transverse connector may itself include a first and a second segment **808, 810** connected by a joint **812**, such as the ball-and-socket type joint shown in FIG. 1.

[0068] FIGS. 9 and 10 show an alternative embodiment for a stabilizing element. As shown in the figures, the stabilizing element includes a first segment **902** having one or more tabs **906, 908** extending upwardly and outwardly from its proximal end. Each of the tabs defines an internal window **907**. Although not explicitly shown in these figures, the first segment also includes a socket of the type shown in FIG. 2 extending into its proximal end. The stabilizing element further includes a second segment **904** having one or more arms **910, 912** extending downwardly and outwardly from its proximal end. Although not explicitly shown in the figures, the second segment also includes an insert of the type shown in FIG. 2 disposed on its proximal end. When the first and second segments **902, 904** are connected to form a joint, the arms **910, 912** of the second segment fit through the windows **907** in the tabs **906, 908** of the first segment **902**. A first spring **914** is disposed around the neck of the second segment to provide for damping of axial loading on the joint. A second and a third spring **916, 918** are disposed around the arms **910, 912** of the second segment **904** in order to provide a damping or restriction of the flexion and extension or lateral motions of the joint. As best seen in FIG. 10, the dimensions of the window **907** is desirably greater than the dimensions of the arm

910 to allow for a certain degree of translation and rotation of the arm **910** within the window **907**.

[0069] FIGS. 11 and 12 depict an embodiment of a pivoting joint that may be used to connect two segments of the stabilizing element in a spinal stabilization system, wherein the stabilizing element is a stabilizing plate. FIG. 11 shows a cross-sectional front view of the stabilizing element. In this embodiment, the plate includes a first segment **1102** having a socket **1105** extending into the proximal end thereof. As best shown in FIG. 12, the proximal end of the plate is expanded in order to accommodate the socket **1105**. This socket **1105** is defined by two opposing concave surfaces **1106**, **1108** separated by a gap **1110**. The socket is further defined by a lower housing **1112** centered on the longitudinal axis of the stabilizing plate and opening into the gap **1110**. The stabilizing plate further includes a second segment **1104** having an insert **1115** on its proximal end. The insert is characterized by two opposing convex surfaces **1116**, **1118** and is desirably, but not necessarily, integrally formed on the proximal end of the second segment **1104**. As shown in the contrasting views of FIGS. 11 and 12, the insert is disc-shaped, that is, it is wider in one dimension than the other. This design is advantageous because it limits the rotation of the joint about its longitudinal axis. The outermost end of the insert **1115** desirably includes a flat extension **1120** while the opposing end forms a neck **1122** in the second segment **1104**. The opposing concave surfaces **1106**, **1108** of the first segment **1102** desirably include a flat strip running laterally through the apex of their concavity. This flat strip allows a certain degree of longitudinal translation between the socket and the insert when the joint is connected. As shown in FIGS. 11 and 12, the two segments **1102**, **1104** of the stabilizing element depicted therein each also include a slot **1122**, **1124** extending through that segment. These slots are adapted to accept connectors, such as bone screws, hooks or nails in order to attach the stabilizing element to a vertebra.

[0070] FIG. 13 shows an embodiment of the stabilizing element of FIG. 3 wherein each of the first and second segments **202**, **204** is composed of a plurality of interconnecting sections **1326**, **1327**, **1328**, **1329**, **1330**. In the embodiment depicted

in FIG. 13, the segments are connected end to end through a series of screw type connections 1332, 1333, 1334. As shown in the figure, one section 1326, 1328 of each segment 202, 204 includes a slot 1336, 1337 extending therethrough for accepting a connector such as a bone screw, hook or nail for attaching the stabilizing element to a vertebra. This embodiment makes it easy to adjust the length of the stabilizing element and to replace the joint sections 1327, 1330 with a rigid rod section in order to convert the pivoting stabilizing element into a rigid stabilizing element.

[0071] FIG. 14 shows a cross-sectional view of a portion of a stabilizing element that includes a compressible joint rather than a pivoting joint. In this embodiment, the stabilizing element includes a first segment 1402 and a second segment 1404. The first segment 1402 includes a piston 1406 extending outwardly from its proximal end. A housing 1408 is defined in the proximal end of the second segment 1404. When the two segments are connected to form a joint, the piston 1406 extends into the housing 1408 and a damping element 1410 is disposed between the distal end 1412 of the piston and the ceiling 1414 of the housing. The damping element depicted in FIG. 14 is a spring. However, any suitable damping element may be used provided that element is capable of damping the axial loading on the joint. Other suitable damping elements include polymer or gel-based elastomeric bumpers. The use of a damping element in the housing 1408 of the second segment 1404 eliminates the need for a damping fluid. This is advantageous because compressible joints that employ a damping fluid run the risk of leaking, causing an irritation, infection or toxicity in the patient.

[0072] FIG. 15 shows an embodiment of a polyaxial pedicle screw 1560, of the type disclosed in U.S. Patent No. 6,626,908, that may be used as a connector in the spinal stabilization systems provided herein. The polyaxial pedicle screw 1560 comprises a pedicle screw 1562, a housing 1564, a saddle shaped element 1566, a set screw 1568, a set screw aperture 1570, and a rod 1572. The pedicle screw comprises a screw stem 1574 and a screw head 1576. The housing 1564 has a through bore with a diameter at the top sufficient to allow the screw stem 1574 and the screw head 1576

of the pedicle screw **1562** through the housing. The through bore diameter narrows at the bottom of the housing **1564** sufficient to allow only the screw stem **1574** through the bottom of the housing **1564**. The saddle shaped element **1566** extends across the width of the housing **1564** and can not be angularly displaced relative to the housing **1564**. The saddle shaped element **1566** has a cylindrical shaped upper surface for engagement with the rod **1572**. The saddle shaped element **1566** also has a spherical lower portion for engaging with the screw head **1576** that has a complementary spherical recess. The set screw **1568** is screwed into the set screw aperture **1570** to clamp the rod **1572** in position relative to the housing **1564**. The engagement between the saddle shaped element **1566** and the screw head **1576** allows the housing **1564** to pivot with respect to the fixed pedicle screw **1562** thereby allowing the rod **1572** to pivot relative to the attachment point.

[0073] FIG. 16 shows a polyaxial hook **1678** that is similar to the polyaxial pedicle screw **1560** of FIG. 15 except that the pedicle screw **1562** has been replaced with a hook **1680** for attaching to the vertebra. The hook **1680** comprises a hook stem **1682** and a hook head **1684**. The hook head **1684** similarly has a complementary spherical recess for engaging with the saddle shaped element **1566** and allowing the housing **1564** to pivot relative to the hook **1680**.

[0074] A second aspect of the invention provides a spinal stabilization system that includes the following basic elements: 1) at least one dynamic stabilizing element; 2) a first connector adapted to connect the at least one dynamic stabilizing element to a first vertebrae in a spinal column; 3) a second connector adapted to connect the at least one dynamic stabilizing element to a second vertebra in the spinal column; and 4) a disc prosthesis or disc nucleus replacement adapted to be inserted into an intervertebral space between two adjacent vertebrae in the spinal column. Each of these basic elements will be described in more detail below.

[0075] Examples of suitable disc prostheses, disc nucleus replacements and connectors for use with the spinal stabilization systems of this aspect of the invention have been discussed previously in this disclosure. The connectors may attach the

stabilizing elements to the same vertebra between which the disc prosthesis or disc nucleus replacement is disposed, or to other vertebra in the spinal column.

[0076] In a first embodiment, in accordance with this aspect of the invention, the dynamic stabilizing element is the dynamic spinal orthosis disclosed in U.S. Patent No. 5,672,175, the disclosure of which is incorporated herein by reference. FIGS. 17 and 18 illustrate a spinal stabilization system that used two spinal stabilizing elements similar to those disclosed in the '174 Patent. Here, the spinal stabilization system includes two dynamic stabilizing elements, each composed of a flexible rod **1702, 1704**. The flexible rods are each attached to one vertebra in a manner that allows the rod to translate longitudinally with respect to that vertebra, where a "longitudinal" translation refers to a translation along the long axis of the spine. The flexible rods are also each attached to another vertebra in a manner that does not allow the rod to translate longitudinally with respect to that vertebra. In the embodiment depicted in FIG. 17, each rod is attached by a first connector **1706, 1708** to a first vertebra **1710** and by a second connector **1712, 1714** to a second vertebra **1716**. Each connector includes a shaft **1718, 1720** (e.g., a nail, pin, hook or threaded screw shaft) that provides a connection to a bone or a prosthetic vertebral body and a securing portion **1722, 1723, 1724, 1725** that provides a connection to the flexible rod. The first connector **1706, 1708** is adapted to provide a rigid attachment to the flexible rod **1702, 1704**, that is, an attachment that prevents relative motion between the flexible rod and the shaft of the connector. In one simple variation of this embodiment, the shaft **1718** of the first connector is a threaded screw shaft adapted to penetrate into a bone **1710** and the rod securing portion is a screw head **1722, 1724** (or nail head or hook head) having a bore **1726** extending therethrough. In this embodiment, the flexible rod **1702, 1704** is inserted through the bore **1726** and locked into a fixed position by one or more transverse set screws **1728, 1729** that screw against, into or through the rod **1702, 1704** after it has been inserted into the bore. In this embodiment, the shaft of the second connector may also be a threaded screw shaft **1720** (or nail shaft or hook) adapted to penetrate into a bone **1716** and the rod securing portion includes a housing **1730** enclosing a coupling member that includes a sphere **1732** having a cylindrical bore **1734** for engagement with the flexible rod

1702, 1704. The coupling member is capable of allowing translation of the flexible rod **1702, 1704** along the axis of the bore. The coupling member may also optionally allow rotation of the flexible rod about the axis of curvature, about an axis perpendicular to the frontal plane, or about an axis perpendicular to the sagittal plane. In the embodiment depicted in FIGS. 17 and 18, the spinal stabilization system further includes a spring **1740, 1742** disposed around each flexible rod **1702, 1704** to allow for axial damping. FIG. 18 shows a cross-sectional lateral view of the spinal stabilization system taken through the plane of attachment. Although not shown, the springs may be enclosed in a housing or sheathed in a tissue growth-resistant material in order to prevent tissue growth from interfering with their operation. As shown in this figure, the system also includes a disc prosthesis **1750**. The illustrative disc prosthesis includes a superior base plate **1752**, an inferior base plate **1754** and a central elastomeric insert **1756**.

[0077] In a second embodiment, in accordance with this aspect of the invention, the spinal stabilization system includes two dynamic stabilizing elements, wherein each dynamic stabilizing element is composed of a damping element and each damping element is a dynamic bias device as disclosed in U.S. Patent No. 6,402,750, the disclosure of which is incorporated herein by reference. In this embodiment of the invention, the two stabilizing elements are disposed in a spaced-apart, substantially parallel relation, typically at the posterior of the spine, on opposite sides of the spinous processes. As described in the '750 Patent, the damping elements may be springs, including coiled springs, leaf springs, articulated leaf springs, torsional springs, torsional leaf springs, or articulated torsional leaf springs. Each damping device is connected across a first and a second vertebra by a first and a second connector, respectively. Suitable connectors include screws, hooks and the like. FIG. 19 illustrates a simple damping element, of the type disclosed in the '750 Patent, that may be used as a spinal stabilizing element. This stabilizing element includes a coiled spring **1902** connected to two wires **1904, 1906** which are themselves connected to a first and a second bone screw **1908, 1910**. The spring **1902** is housed within a housing **1912** to prevent tissue growth from interfering with the spring **1902**.

[0078] FIGS. 20-22 show examples of possible attachment locations for the stabilizing elements of FIG. 19. FIG. 20 shows a first stabilizing element **2002** and a second stabilizing element **2003** attached to the anterior spinal column across a first vertebra **2004** and a second vertebra **2006**. The first stabilizing element **2002** is attached to the first vertebra **2004** using a first connector **2010** and to the second vertebra **2006** using a second connector **2012**. The second stabilizing element **2003** is attached to the first vertebra **2004** using third connector **2014** and to the second vertebra **2006** using fourth connector **2016**.

[0079] FIG. 21 and FIG. 22 show two additional possible attachment configurations for the first and second stabilizing elements **2002**, **2003** of FIG. 20. In FIG. 21, the stabilizing elements **2002**, **2003** are attached to the spinous processes **2100** of two adjacent vertebrae **2106**, **2108**, symmetrically about the sagittal plane and parallel to the axis of curvature. FIG. 22 shows the two stabilizing elements **2002**, **2003** attached across the facet joints **2202**, **2204** of two adjacent vertebrae **2206**, **2208**.

[0080] In order to prevent tissue growth from interfering with the moving parts, such as joints or springs, of the stabilizing elements and stabilization system provided herein, it is advantageous to sheath such parts with a tissue-growth resistant material.

[0081] The components of the various stabilizing elements and stabilization systems provided herein may be constructed from biologically compatible materials. Many such materials are known. These include, but are not limited to, metals, such as titanium, titanium alloys, chrome cobalt or stainless steel. Other biocompatible materials include graphite and ceramics, such as hydroxapatites. Plastics may also be employed. Suitable plastics include polyethylene (e.g., ultrahigh molecular weight polyethylene) and polyether ester ketone.

[0082] The invention has been described with reference to very specific and illustrative embodiments. However, it should be understood that many variations and modifications may be made while remaining within the spirit and scope of the invention.